# The Jackson Heart Study (JHS)

### **Coordinating Center Sources Sought Notice**

# HHS-NIH-NHLBI-SBSS-HHSN26818HV00006R AND HHSN26818HV00006R

# **Contracting Office Address**

Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute, Rockledge Dr. Bethesda, MD, Office of Acquisitions 6701 Rockledge Dr RKL2, Bethesda, MD, 20892-7902, United States

#### Introduction

This is a Small Business Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under NAICS code 541712 should not submit a response to this notice.

#### **Background**

The Division of Cardiovascular Sciences of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), is conducting a market survey to assess the availability and potential technical capability of small business firms to perform as the Coordinating Center as part of the renewal of the program entitled "Jackson Heart Study (JHS)". NHLBI plans to support one Coordinating Center, one Field Center, one Community Outreach Center, and up to two (2) Training Centers. THIS NOTICE ADDRESSES THE JACKSON AREA COORDINATING CENTER (CC) ONLY.

The Jackson Heart Study (JHS), initiated in 1998, is a longitudinal investigation of genetic and environmental risk factors associated with the disproportionate burden of cardiovascular disease (CVD) in African-Americans. In addition, the JHS performs a variety of community education and outreach activities to promote healthy lifestyles

and reduce disease risk burden. It also conducts college undergraduate and graduate-level training programs and high school science and math enrichment programs to prepare and encourage underrepresented minority students to pursue biomedical careers. (<a href="https://www.jacksonheartstudy.org/">www.jacksonheartstudy.org/</a>).

The JHS represents an expansion of the Jackson Field Center of the Atherosclerosis Risk in Communities (ARIC) study (<a href="www2.cscc.unc.edu/aric/">www2.cscc.unc.edu/aric/</a>), to broaden data collection in an African-American population and to increase access to and participation of African American populations and scientists in biomedical research and professions. The study recruited 5306 African-American residents, including 3,732 residents also enrolled in ARIC, living in the Jackson, MS, metropolitan area of Hinds, Madison, and Rankin Counties. Enrolled JHS participants, initially aged 20 - 90 years, received three back-to-back examinations (Exam 1, 2000-04; Exam 2, 2005-08; and Exam 3, 2009-13) and have been contacted annually.

The wealth of data and biological samples collected since the study's inception as well as the potential for new data collection from JHS participants offer vast opportunities for new scientific discoveries. Participant exams have produced extensive longitudinal data on traditional and putative CVD risk factors, socioeconomic and sociocultural factors, and biochemical analytes; and measures of subclinical disease from echocardiography, cardiac magnetic resonance imaging (MRI), and computed tomography (CT) scans of the heart, aorta, and abdomen. Stored biological samples have been assayed for putative biochemical risk factors and stored for future research. DNA has been extracted and lymphocytes cryopreserved for study of candidate genes, genome-wide scanning, expression, and other –omics investigations.

### **Objectives**

The goal of the renewal of the JHS program is to maximize use of data and samples amassed over 16 years to address new questions about the development and progression of clinical CVD and related conditions. The JHS renewal will continue novel epidemiologic research on cardiovascular (CV) and related diseases in this cohort, serve as a resource to the scientific community for future research, promote cardiovascular health in the local community, and encourage underrepresented minority students to pursue biomedical careers. The scientific objectives are to (1) investigate factors that account for the high burden of CVD in African- Americans, with specific focus on factors related to ventricular dysfunction and heart failure and impaired cognitive function; and (2) improve statistical power for further risk prediction and hypothesis testing, particularly in informative subgroups. The operational goals are to (1) continue to foster scientific collaborations; work collaboratively to (2) provide cohort follow-up and clinical events ascertainment activities; (3) conduct a clinic examination of the JHS participants; (4) promote cardiovascular health in the local community; and (5) encourage underrepresented minority students to pursue biomedical careers.

# **Project Requirements**

Throughout the period of performance, the important overall technical requirements associated with the acquisition for the JHS Coordinating Center include the following:

- 1. Designate personnel and staff to lead and conduct the study who have expertise and skills in areas relevant to the study, including but not limited to research in human subjects, cardiovascular disease epidemiology, clinical cardiovascular disease, heart failure, cognitive decline and dementia, longitudinal studies management, biostatistics, human genetics and genomics, and administrative and laboratory management. Designate a principal investigator with research training and experience in cardiovascular epidemiology, demonstrated excellence as a manager and collaborator, and experience in longitudinal cohort study management. Designate a co-investigator(s) knowledgeable in scientific areas relevant to the study and skilled in study design and data analysis. Designate other staff as needed to perform the required work.
- 2. Facilitate regular follow-up contacts of participants by the Field Center, including establishing and maintaining a data collection system.
- 3. Support classification of study endpoints, including the field center's abstraction of records obtained to investigate potential study endpoints and the subsequent review and classification thereof.
- 4. Facilitate a re-examination of the JHS participants by the Field Center. Work closely with ancillary study investigators to coordinate exam components from multiple funding sources.
- 5. Work cooperatively with the ARIC study investigators in all relevant aspects of study development and execution to maximize the cost-effectiveness of the study operations and to minimize the burden to the Jackson participants who enrolled in both JHS and ARIC.
- 6. Perform administrative, operational, and technical duties to support productive collaboration among the study personnel at all JHS Centers, outside researchers collaborating with JHS, and the NHLBI Project Office.
- 7. Establish and maintain study databases, including updating the databases with data from newly ascertained events, Exam 4, and ancillary studies both for study use and for posting on NIH databases, as appropriate.
- 8. Establish and maintain a central laboratory/biological specimen and imaging repositories.
- 9. Coordinate and participate collaboratively in study committees.
- 10. Design and implement appropriate quality assurance and quality control programs.
- 11. Conduct statistical analyses and prepare JHS data-driven scientific publications and presentations that are first-authored by CC investigators.
- Provide formal and/or informal training opportunities for early career investigators, fellows, and/or students, particularly those from underrepresented racial and ethnic groups.
- 13. Prepare and submit technical and other required reports.

- 14. Work cooperatively with all JHS and collaborating investigators and staff, the JHS Director, NHLBI Project Office, and any subcontractors and consultants in all relevant aspects of the study development and execution.
- 15. Perform activities related to study closeout as directed by the NHLBI Project Office.

# **Anticipated Period of Performance**

The Government intends to negotiate one contract for the potential period of six years with an approximate award date of August 16, 2018.

# **Capability Statement**

Small business firms that believe they possess the capabilities necessary to undertake this work should submit complete documentation of their capabilities to the Contracting Officer. The capabilities statement **must** specifically address **each** project requirement separately. Additionally, the capability statement should include 1) the total number of employees, 2) the professional qualifications of scientists, medical experts, and technical personnel as it relates to the above outlined requirements, 3) a description of general and specific facilities and equipment available, including computer equipment and software, 4) an outline of previous research projects that are similar to the project requirements in which the organization and proposed personnel have participated, and 5) any other information considered relevant to this program. The capability statement must not exceed 15 single sided or 7.5 double sided pages in length and using a 12-point font size minimum.

Interested small business organizations are required to identify their size standards in accordance with the Small Business Administration. The government requests that no proprietary or confidential business data be submitted in a response to this notice. However, responses that indicate the information therein is proprietary will be properly safeguarded for Government use only. Capability statements must include the name and telephone numbers of a point of contact having authority and knowledge to discuss responses with Government representatives. Capability statements in response to this market survey that do not provide sufficient information for evaluation will be considered non-responsive. When submitting this information, please reference the solicitation notice number.

### **Point of Contact:**

Mark Brady, Contracting Officer, NHLBI, Office of Acquisitions, phone: (301) 827-7532, email: mark.brady@nih.gov

Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute, Rockledge Dr. Bethesda, MD, Office of Acquisitions

#### **Submission Instructions:**

Interested parties shall submit capability statements via the FedConnect web portal (www.fedconnect.net) and reference the FedConnect Sources Sought Number HHSN26818HV00006R. The due date for receipt of statements is **3:00 PM Eastern Time on Wednesday, April 26, 2017**. Vendors can register with FedConnect at <a href="https://www.fedconnect.net/FedConnect/default.htm">https://www.fedconnect.net/FedConnect/default.htm</a>.

Please note that FedConnect is used by multiple federal agencies and therefore FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect Ready, Set, Go! Guide at <a href="https://www.fedconnect.net/fedconnect/Marketing/Documents/FedConnect Ready Set Go.pdf">https://www.fedconnect.net/fedconnect/Marketing/Documents/FedConnect Ready Set Go.pdf</a>.

For assistance in registering or for other FedConnect technical questions please call the FedConnect Help Desk at (800) 899-6665 or email at support@fedconnect.net. Please use the Contracting Officer/ Contract Specialist contact information provided, should you require a waiver not to use FedConnect for submitting.

All responses must be received by the specified due date and time in order to be considered.

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in the response. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After review of the responses received, pre-solicitation and solicitation notices may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.